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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,261	12/06/2000	Joel F. Habener	17633/1230	9060

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/731,261	HABENER ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,21-29 and 42-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,21-29,43 and 44* is/are rejected.

7)☒ Claim(s) *42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/6/04 has been entered. Applicant's response and the declaration under 1.132 by Dr. Habener filed on concurrently with the RCE have also been entered. Claims 1-18, 20, and 30-41 have been canceled. New claims 42-44 have been added. Claims 19, 21-29, and 42-44 are currently pending and under examination in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in previous office actions.

Priority

Priority to applicant's provisional applications is acknowledged.

Claim Rejections - 35 USC § 112

The rejection of claims 19-21 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps is withdrawn in view of applicant's amendment and/or

cancellation of the claims. Please note that while the declaratory evidence presented in the declaration by Dr. Habener has been fully considered, the post-filing evidence for additional methods to isolate nestin-positive cells was not relied upon in overcoming the instant rejection of record as the methods discussed in the declaration are not disclosed in the specification. The amendment to the claims which identifies nestin-positive cells as cells which have migrated from the islet under the appropriate culture conditions has overcome the rejection of record.

Claim 43 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. New claim 43 recites in step (c), " transferring cells from step (b) to a second vessel not coated with concanavalin A". However, in step (b) two cells populations are present, the adherent population and the non-adherent population. It is unclear which of these cells populations are to be transferred to the second vessel.

Claim 44 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. New claim 44 recites, " The isolated nestin-positive human pancreatic stem cell, wherein said stem cell is isolated by the method of claim 19 or claim 43". There is no antecedent basis for a nestin-positive **human** pancreatic stem cell in the methods of claims 19 or 43. Neither of these methods identifies the species of the donor or the species of the stem cell produced from these methods. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The rejection of claims 22-23 under 35 U.S.C. 102(a) as being anticipated by Stoffers et al. (2000), Diabetes, Vol. 49, 741-748, is withdrawn as applicant's have perfected priority to provisional application No. 60/169,082, which has a filing date of 12/6/99.

The rejection of claims 24-29 under 35 U.S.C. 102(e) as being anticipated by U.S. patent No. 6,436,704 (8/20/02), hereafter referred to as Roberts et al., is withdrawn as applicant's have perfected priority to provisional application No. 60/169,082, which has a filing date of 12/6/99.

The rejection of claims 22-23 under 35 U.S.C. 102(b) as being anticipated by Xu et al. (1999) Diabetes, Vol. 48, 2270-2276, is withdrawn in view of applicant's amendment of the claims to recite that the stem cell is "isolated".

Claims 24-29, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/15310 (5/1/97), hereafter referred to as Peck et al.. The applicant claims isolated, nestin-positive human pancreatic or liver stem cells that are not neural stem cells. The applicant further claims said cells, wherein the cells do not express MHC class I, or wherein the cells differentiate to form beta cells, alpha cells, pseudo-islet like aggregated, or hepatocytes. While it is noted that claim 44 is a product by process claim, the applicant is reminded that, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its

method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Thus, for the purposes of prior art, claim 44 reads on an isolated nestin-positive human pancreatic stem cell.

Peck et al. teaches isolated pancreatic stem cells, including isolated human pancreatic stem cells, wherein the pancreatic stem cells can be induced to differentiate into mature cell types such as insulin-producing beta cells, glucagon producing alpha cells, and are further capable of producing islet like aggregates comprising different mature cell types (Peck et al., pages 14-15, 22, 28-29, and page 50, claim 39). While Peck et al. does teaches methods for identifying marker proteins specific to pancreatic stem cells versus more differentiated cell types, see pages 32-35, and also teaches isolating pancreatic stem cells based on specific marker proteins, see pages 35-36, Peck et al. does not specifically teach that nestin is a marker for pancreatic stem cells. However, since Peck et al. teaches pancreatic stem cells and further teaches that these cells have the same capacity to differentiate into more mature cell types as nestin positive pancreatic stem cells disclosed in the instant specification, nestin expression by pancreatic stem cells is considered an inherent property of the stem cells disclosed by Peck et al.. The applicant is reminded that , "When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent." See MPEP 2112.01 or In re Best, 195 USPQ 430, 433 (CCPA 1997). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural

and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989). Thus, the human pancreatic stem cells disclosed by Peck et al. anticipate the instant invention as claimed.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 24-28 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 39 and 43 of copending Application No. 09/963,875, hereafter referred to as the '875 application.

Claim 39 of the '875 application and instant claim 24 are identical. Claim 43 further recites the identical limitations recites in instant claims 25-28. The claims 24-28 claim the same invention as claim 39 and 43 of the '875 application.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19, 21-23, 29, and 43-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39-43 of copending Application No. 09/962,875, hereafter referred to as the '875 application. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. The '875 claims recites broader methods than those recited in instant claims 19, 21-23, and 43. However, the additional steps listed in the instant claims are clearly set forth in the specification of the '875 patent and thus are clearly encompassed by the '875 claims. The same applies to the stem cell claims. The '875 claims recite broader stem cells than those recited in instant claims 29 and 44. However, the specification of the'875 application clearly teaches the exact limitations as characteristics of the pancreatic stem cells and thus the cells recited in the

'875 claims encompass those recited in the instant claims. Thus, the broader claims of the '875 patent render obvious the instant method claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 42 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER